REMARKS/ARGUMENTS

This is in response to the Office Action dated March 13, 2009. This response is accompanied by a request for a three month extension of time and the associated fee of $555.00. Accordingly, the applicant requests that this response be considered timely filed.

This amendment does not add new matter. Amendments to claim 1 are supported, among other places, in the passages described in the remarks below.
The circuit claims 15, 16 and 17, are now cancelled, without prejudice.

35 U.S.C. 101 / 35 U.S.C. 112

In this response, the claims have been amended to better define the invention, and to address the objections of the Examiner based on 35 U.S.C. 101 and 35 U.S.C. 112. In particular, the claims have been reformulated to define traditional statutory subject matter; claim 1 and claims dependent thereon are now directed to method of determining the flux of a gas "X" in a subject, and new claims 25 to 29 are also directed to traditionally patentable subject matter. The language cited by the Examiner as offending 35 U.S.C. 112 has been deleted or replaced.

35 U.S.C. 103(a)

The art cited by the Examiner does not disclose the invention defined in the claims as explained below. From page 4, line 6-7 it is clear that the gas flux referred to in the claims is the amount of a particular gas being consumed or eliminated via the lung . It is submitted that it is not at all obvious, as explained below, that the rate that a gas "X" is being consumed or eliminated via the lung can be determined without collecting gas leaving the circuit, and can be made to amenable to a determination under predefined

conditions compatible with treating a subject without needing specialized equipment or continuously tracking incremental concentration and volume changes.

In particular, the invention is predicated on the discovery that the flux of any gas "X" in a CBC circuit (Conditional Breathing Circuit - see page 2 lines 7 to 9) can be far more readily determined without the inconvenience of measuring exhaled gas volumes or other inconveniences described at page 3, line 10 to page 4, line 19.

Since the patient is breathing on a circuit in which the first portion of the subject's breath is a gas with a known concentration of gas "X" and in which this gas is flowed to the subject in an amount which results in gas entering the circuit being less than the subject's alveolar ventilation, the balance of the gas in that breath already being equilibrated with the subject's alveoli (for example gas exhaled by the subject which has the same concentration of gas "X" as in the alveoli and is therefore neutral from the standpoint of flux - no flux of gas "X" occurs due to this part of the breath), the amount of gas flowed to the subject is determinative of the alveolar ventilation (the volume of gas per unit time that is exchanged across the alveoli).

In these circumstances, and not under the condition disclosed or defined in the cited references, it has been discovered that calculating the flux becomes a matter of multiplying this rate of gas exchange (which is equivalent to the SGF (Source gas flow - see page 1 line 18)) by the difference in the fractional concentration of gas "X" in the source gas and the expired gas. The notion that the principles described above can be simply implemented as aforesaid is described at page 10, lines 10 to 12. These principles are disclosed as conditions required for the operation of the invention at page 11, lines 4 to 14.

Additional explanation of the principles underlying the operation of the invention with respect to the properties of the CBC circuit follows:

The embodiment of the invention characterized in current claim 1 is a method of

determining the flux of any gas using a particular type of breathing circuit - a CBC (defined at page 2, line 7) - which could be used when a spontaneously breathing patient is undergoing anaesthesia or which could be provided to a ventilated patient to breathe on.

A CBC is defined at page 2 as a breathing circuit in which the source gas flowed to the patient does not escape the circuit; only exhaled gas leaves the circuit. Therefore, since the volume of expired gas is not being measured (this is obviated by the contribution of the inventors) and the choice of circuit also obviates concern about what blend of inspired and exhaled gases is leaving the circuit (flux is therefore not affected by this variable), and alveolar ventilation is being controlled by the gas flow setting, the invention need only be concerned with the product of the inflow rate and the concentration difference between SGF and the end tidal gas.

As noted at page 1, lines 5-8 in the Field of the Invention, the method applies to gases that are taken up or consumed by a patient and those, such as carbon dioxide, that are eliminated by the patient:

'This invention relates to a method of measuring uptake and elimination via the lung of all gases for example including, but not limited to, anaesthetics, oxygen and carbon dioxide."

The formulae for calculating the flux of any gas in question applicable in the case of elimination: SGF x (FEX - Fsx) set forth at page 11, line 19 is substantially identical to the one for the case of uptake: SGF x (Fsx - FEX) set forth at page 13, line 8; the only difference being the different order of the term FEX (relative to Fsx) in the brackets. In the case of elimination of gas "X" (where the concentration of gas "X" in the expired gas is higher due to the elimination) FEX is first and in the case of uptake of gas "X" (where the concentration of gas "X" in the expired gas is lower due to the uptake) FEX is second – so that the multiplier in brackets is in both cases is a positive number. The

third formula in claim 1 is supported in original claim 11 and at pages 41-42 of the specification.

New claims 25 to 29 also find support in the various passages recited above and represent different aspects of the same inventive concept.

It is submitted that the Rydin and Dittmann references cited by the Examiner do not disclose or even suggest the invention discussed above. Without appreciating the nature of invention as described above, neither the advantageously simplified combination of circuit elements including a CBC, gas flow controller and end tidal gas flow sensor (not more) nor the correct gas flow settings (controlling alveolar ventilation), that synergistically combine to obviate the need to collect gas nor the resulting amenability to a formula or the nature of the formula, could reasonably be asserted to be obvious from the cited references.

Rydin et al. is concerned a different problem - with measuring gas pressure and flow resistance in a breathing circuit and does not suggest itself as a source for the solution of the problem addressed by the invention nor as an impetus to use the combination of the above elements. The Examiner asserts that the method Rydin is used in a "breathing circuit", as though the nature of the breathing circuit is indifferent. The nature of breathing circuit and why and how it works, is not indifferent as explained above, nor more importantly are the inventive implications of using one circuit relative to another in synergistic combination with other elements of the invention to obviate the need for gas collection.

With particular reference to Dittmann et al., the present invention, in contrast to Dittmann, is not concerned with a feedback mechanism for continuously controlling gas concentration by monitoring and adjusting gas flows based on measured concentrations. The passages in Dittmann et al. cited by the Examiner teach away from the instant invention.

Claims 15 and 17 have been cancelled, without prejudice, and therefore the prior art references applied by the Examiner in support of a rejection of these claims are moot and are not addressed in this Amendment.

The following is a concise explanation of the relevance of the foreign language patents included in the IDS filed 2/29/2009. It is noted that these patents were brought to the Applicant's attention in virtue of being cited by PCT search authority as being of interest (code A - but not on the grounds of novelty or inventive step):

JP2003346214 discloses a balloon valve of the type exemplifying a valve referred to in dependent claim 4 that could be useful, for example, to occlude a port configured to bring a breathing circuit into fluid communication with atmosphere.

FR 2 784 587 relates to a breathing circuit comprising a balloon valve, in which the valve is instrumental to provide variable positive end expiratory pressure. In a respiratory assistance apparatus, of a type including a pressurized source of air continuously providing pressurized air, the apparatus including an expiratory valve (32) implemented in the form of a balloon valve in which is created a regulated pressure for determining an opening degree of the valve (32), characterized in that, in the expiratory phase, the expiratory valve (32) is likely to be fed in pressurized air coming from the pressure source (12) by a command circuit (34) provided with a regulated discharge valve (44) by which part of the air flow coming from the pressure source (12) is evacuated from the command circuit (34) in order to regulate the pressure in the expiratory valve (32).

FR 2 784 297 discloses a respiratory assistance process and apparatus comprising at least one inspiratory branch (7) joining respiratory gas providing means (T1, T2, 20) to the respiratory branches of a user, said respiratory gas providing means (T1, T2, 20) comprising at least one first respiratory gas source

(T1) and at least one second respiratory gas source (T2), characterized in that during at least part of at least one inspiratory phase, said first and second respiratory gas sources (T1, T2) are pneumatically joined in series and in that communication means controlled by piloting means (16) allow the joining, in a relatively air-tight fashion, of said first and second respiratory gas sources joined pneumatically in series to said inspiratory branch (7) to allow the feeding of said inspiratory branch (7) with respiratory gas.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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